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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,544	10/03/2001	Jean-Pierre Chervet	A-70881/DJB/MAK	1387

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EXAMINER

LUDLOW, JAN M

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 09/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No

09/970,544

Applicant(s)

CHERVET ET AL.

Examiner

Jan M. Ludlow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 June 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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1. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-17 are unclear as to the scope of the claims in that the claims are replete with references to the liquid chromatography setup recited in the preamble and not a positively recited element of the claims. For example, claim 1 recites a micro switching valve unit and a secondary pump system (which are not even operatively coupled) and nothing more. The "first flow rate" recited relative to the valve unit is dependent upon the chromatographic set up, not the valve unit—any multiport micro valve unit having two positions and any pump unit that can be coupled to that valve unit satisfies the limits of the claim, because any multiport micro valve and pump can be configured to satisfy the functional limitations relative to the unclaimed elements. Similarly, the "wherein..." clause relates to an intended method of use, not a structural limitation. In claim 2, the control unit is positively recited, but is coupled to the post column detector, which is not a positively recited element of the invention. See also claim 13. Claims 3, 5, 6, 8-12 all provide limitations to the setup (not claimed) and method of use which do not clearly further limit the structure of the valve, pump and controller, the only positively recited elements of the claims. If applicant merely intends, e.g., that the controller is capable of outputting a signal which can be input to an NMR or MS (claim 9), or that the valve is capable of passing a first flow rate of 50-400 nl/min (claim 8), then the claims are sufficiently clear. However, in order to meet the limitations, the prior art does not have to actually teach a method, e.g., in which a first

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flow rate is 50-400 nl/min, because such has not been claimed. In claim 11, line 4, "gradient composition is maintained" is unclear—is maintained as what?

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 1, 6, 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Jorgenson et al.

Jorgenson teaches a 6 port valve 10, coupled to pump 40 and detector 51. A controller is coupled to the valve and detector for operating the valve in response to the detector. Note that while Jorgenson uses the apparatus for a different method, the instant claims do not preclude the additional features, nor do they require an LC column operating at a first flow rate greater than the flowrate of the pump. The pump is structurally capable of the claimed function, i.e., pumps slower than some other arbitrary flowrate, produced by an unclaimed LC column.

7. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jorgenson as applied to claim 1.

Jorgenson fails to teach the controller coupled to the pump.

It would have been obvious to couple the controller to the pump in order to fully automate the operation of the apparatus as was known in the art.

8. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al (J. Am. Soc. Mass Spectrom. 1997, vol. 8, pp. 1059-69).

9. Davis et al teaches a method of analyzing effluent from an LC. Flowrate is reduced when a peak of interest is detected, and flowrate returned to normal when analysis is complete (Abstract, p. 1064-65).

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10. Claims 16, 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spraul et al.

Spraul teaches a method and apparatus for peak parking between a liquid chromatograph and detectors, such as NMR and/or MS. Control software can take information from the MS detector to make decisions for further action and mode selection (col. 9, lines 23-25). Samples passing through a low dead volume multiport valve unit 38 are passed to the detector(s) at a flow rate slower than the chromatographic speed by a dilution pump 86, shown as a syringe pump (col. 10, lines 46-50, col. 12, lines 40-45). Although the specific examples involve sample loop collection, the device can also be used in stopped flow mode (col. 9, line 52).

Spraul fails to explicitly teach an embodiment using stopped-flow mode.

It would have been obvious to stop flow through the column during peak analysis using the slower flow rate of pump 86 and resume flow after peak analysis in order to operate in stopped-flow mode as taught by Spraul. In that Spraul teaches devices and methods substantially as disclosed, it is the examiner's position that the claimed pressure and/or gradient maintenance is inherent. With respect to specified flow parameters, it would have been obvious to optimize the result effective-variable of flow rate in order to optimize separation and/or detection quality and/or time.

11. Claims 4-5, 7-12, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spraul as applied to claims 13, 16-20 above, and further in view of EP 0495255.

Spraul fails to teach a micro valve, micro pump or flow splitter.

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EP teaches a miniature chromatographic system including a flow splitter to provide reduced flow rates to a micro column.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a micro valve and micro pump in the invention of Spraul in order to perform small scale separation and analysis as taught by EP. Note that applicant admits that the instant micro valve is commercially available. With respect to claims 10-11, note first that the gradient producer and flow splitter are not positively recited. Nevertheless, it would have been obvious to provide a flow splitter and gradient former in order to provide gradient elution to the modified column of Spraul in order to provide accurate chromatographic flow to a small scale column as taught by EP.

12. Applicant's arguments filed June 9, 2003 have been fully considered but they are not persuasive.

Applicant does not understand the examiner's statement that in claim 1, the valve and pump system are not operatively coupled, but goes on to state that "the pump system was stated to be **coupleable** [emphasis added] to a portion of the micro switching valve unit..." "Coupleable" and "coupled" are not the same thing. Further, applicant argues that the micro switching valve was recited to be in fluid communication with the eluent of the LC system, but in that the LC system is not claimed, the recitation that the valve is coupled to the LC system does not limit the claim. The invention as claimed ends at the valve; what it is coupled to is not part of the invention. Further, in claim 1 as amended, the valve is not recited as being in fluid communication with the eluent, but once again "coupleable" to be in fluid communication with the eluent.

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Similarly, the recitations of relative flow rates, especially relative to the unclaimed LC system, are not seen as structural or functional limitations of the claimed valve and pump. Whether the claimed pump slows the flow rate is dependent upon the pumping rate of fluid introduced into the post column system by the LC pump, and since neither the LC pump nor a controller for the LC pump setting a first flow rate is claimed, the functional limitation of the claimed pump slowing flow is nearly meaningless. It is suggested that applicant carefully read the rejection under 35 USC 112, second paragraph and the claims, and amend the claims so that they describe structural/functional limitations of the valve, pump and controller, not to the unclaimed LC system and its components or to intended use. Alternatively, the LC system may be positively recited, providing antecedence and meaning to the features described relative to the LC system, and the method steps recited as functional limitations of the controller.

Applicant argues that Spraul does not qualify as prior art. This is true for claims 1-3, 6, 13 and 18, which are supported by the provisional application, but not claims 4-5, 7-12, 14-17 and 19-20, which contain one or more limitations not supported in the provisional application. The examiner regrets the error in citing the Spraul reference against all of the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jan M. Ludlow whose telephone number is (703) 308-4039. The examiner can normally be reached on Monday-Thursday, 11:30 am - 8:00 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.



Jan M. Ludlow
Primary Examiner
Art Unit 1743

Jml
August 25, 2003